IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVO NORDISK INC. and NOVO NORDISK A/S,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
SANDOZ INC.,	)	
Defendant.	)	

COMPLAINT

Novo Nordisk Inc. and Novo Nordisk A/S (collectively, "Novo Nordisk"), by their undersigned attorneys, for their Complaint against Defendant Sandoz Inc. ("Sandoz"), allege:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35 of the United States Code, arising from Sandoz's submission of an Abbreviated New Drug Application ("ANDA") to the United States Food and Drug Administration ("FDA"), by which Sandoz seeks approval to market a generic version of Novo Nordisk's pharmaceutical product Victoza® prior to the expiration of United States Patent Nos. 6,268,343 (the "'343 patent"), 7,762,994 (the "'994 patent"), 8,114,833 (the "'833 patent"), 8,579,869 (the "'869 patent"), 8,846,618 (the "'618 patent"), and 9,265,893 (the "'893 patent"), which cover inter alia, Victoza® and/or its use.

THE PARTIES

2. Plaintiff Novo Nordisk Inc. ("NNI") is a corporation organized and existing under the laws of the State of Delaware, and has its principal place of business at 800 Scudders Mill Road, Plainsboro, New Jersey, 08536.

3. Plaintiff Novo Nordisk A/S ("NNAS") is an entity organized and existing under the laws of the Kingdom of Denmark, and has its principal place of business at Novo Allé, 2880 Bagsværd, Denmark. NNI is an indirect, wholly-owned subsidiary of NNAS.

4. On information and belief, Defendant Sandoz Inc. is a corporation organized and existing under the laws of the State of Colorado, having its principal place of business at 100 College Road West, Princeton, NJ 08540. On information and belief, Sandoz Inc. is in the business of making and selling generic pharmaceutical products, which it distributes in the State of Delaware and throughout the United States.

THE PATENTS-IN-SUIT

5. On July 31, 2001, the United States Patent and Trademark Office issued the '343 patent, entitled "Derivatives of GLP-1 Analogs," a copy of which is attached to this Complaint as Exhibit A. NNAS is the owner of all right, title, and interest in the '343 patent.

6. On July 27, 2010, the United States Patent and Trademark Office issued the '994 patent, entitled "Needle Mounting System and a Method for Mounting a Needle Assembly," a copy of which is attached to this Complaint as Exhibit B. NNAS is the owner of all right, title, and interest in the '994 patent.

7. On February 14, 2012, the United States Patent and Trademark Office issued the '833 patent, entitled "Propylene Glycol-Containing Peptide Formulations Which Are Optimal for Production and For Use in Injection Devices," a copy of which is attached to this Complaint as Exhibit C. NNAS is the owner of all right, title, and interest in the '833 patent.

8. On November 12, 2013, the United States Patent and Trademark Office issued the '869 patent, entitled "Needle Mounting System and a Method for Mounting a Needle

Assembly," a copy of which is attached to this Complaint as Exhibit D. NNAS is the owner of all right, title, and interest in the '869 patent.

9. On September 30, 2014, the United States Patent and Trademark Office issued the '618 patent, entitled "Stable Formulation of Modified GLP-1," a copy of which is attached to this Complaint as Exhibit E. NNAS is the owner of all right, title, and interest in the '618 patent.

10. On February 23, 2016, the United States Patent and Trademark Office issued the '893 patent, entitled "Injection Button," a copy of which is attached to this Complaint as Exhibit F. NNAS is the owner of all right, title, and interest in the '893 patent.

VICTOZA®

11. NNI holds approved New Drug Application No. 022341 (the "Victoza® NDA") for Liraglutide Recombinant Solution Injection, 18 mg/3 ml (6 mg/ml), which NNI sells under the trade name Victoza®.

12. The claims of the patents-in-suit cover, inter alia, Victoza® and/or its use.

13. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '343, '994, '833, '869, '618, and '893 patents are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to Victoza®.

SANDOZ'S ANDA

14. On information and belief, Sandoz submitted ANDA No. 212972 ("Sandoz's ANDA") to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market a generic version of liraglutide injection solution, 18 mg/3 ml (6 mg/ml) ("Sandoz's Product").

15. On information and belief, Sandoz's ANDA refers to and relies upon the Victoza® NDA and contains data that, according to Sandoz, demonstrate the bioequivalence of Sandoz's Product and Victoza®.

16. By letter to NNI and NNAS, dated April 20, 2020 and sent via FedEx Priority Overnight Service (the "Notice Letter"), Sandoz stated that Sandoz's ANDA contained certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the '343, '994, '833, '869, '618, and '893 patents are invalid, unenforceable, or will not be infringed by the commercial manufacture, use, or sale of Sandoz's Product (the "Paragraph IV Certifications"). Sandoz attached a memorandum to the Notice Letter in which it purported to allege factual and legal bases for its Paragraph IV Certifications. NNI and NNAS file this suit within 45 days of receipt of the Notice Letter.

JURISDICTION AND VENUE

17. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

18. This Court has personal jurisdiction over Sandoz by virtue of, inter alia, it having conducted business in Delaware; having derived revenue from conducting business in Delaware; previously consenting to personal jurisdiction in this Court; having taken advantage of the rights and protections provided by this Court, including having asserted counterclaims in this jurisdiction (*see, e.g.*, *Merck Sharp & Dohme Corp. v. Sandoz Inc.*, No. 19-312 (D. Del.); *Otsuka Pharm. Co., Ltd. v. Sandoz Inc.*, No. 19-2080 (D. Del.)); and having engaged in systematic and continuous contacts with the State of Delaware.

19. On information and belief, Sandoz intends to sell, offer to sell, use, and/or engage in the commercial manufacture of Sandoz's Product, directly or indirectly, throughout the United States and in this District. Sandoz's filing of Sandoz's ANDA confirms this intention and subjects Sandoz to the specific personal jurisdiction of this Court. *See Acorda Therapeutics, Inc.*

v. Mylan Pharms., Inc., 817 F.3d 755, 759-60 (Fed. Cir. 2016), *cert. denied*, 137 S. Ct. 625 (2017).

20. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 6,268,343

21. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-20 of this Complaint.

22. Sandoz has infringed the '343 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Sandoz's ANDA, by which Sandoz seeks approval from the FDA to sell, offer to sell, use, and/or engage in the commercial manufacture of Sandoz's Product prior to the expiration of the '343 patent.

23. Claims 1-3 and 14 of the '343 patent encompass liraglutide; claims 28, 29, 31, 32 and 33 of the '343 patent encompass pharmaceutical compositions comprising liraglutide; and claim 39 of the '343 patent encompasses a method of treating diabetes comprising administering to a patient a therapeutically effective amount of liraglutide. Sandoz's sale, offer for sale, use, or commercial manufacture of Sandoz's Product within the United States, or importation of Sandoz's Product into the United States, during the term of the '343 patent would infringe at least claims 1-3, 14, 28, 29, 31, 32, 33, and 39 of the '343 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

24. Upon information and belief, Sandoz's sale or offer for sale of Sandoz's Product within the United States, or importation of Sandoz's Product into the United States, or commercial marketing of Sandoz's Product in the United States, during the term of and with knowledge of the '343 patent, would intentionally induce others to use Sandoz's Product in the United States, thus inducing infringement of claim 39 of the '343 patent.

25. Novo Nordisk will be harmed substantially and irreparably if Sandoz is not enjoined from infringing the '343 patent.

26. Novo Nordisk has no adequate remedy at law.

27. Novo Nordisk is entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 7,762,994

28. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-27 of this Complaint.

29. Sandoz has infringed the '994 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Sandoz's ANDA, by which Sandoz seeks approval from the FDA to sell, offer to sell, use, and/or engage in the commercial manufacture of Sandoz's Product prior to the expiration of the '994 patent.

30. Claims 1-8 of the '994 patent encompass a mounting system for mounting two different needle arrangements. Sandoz's sale, offer for sale, use, or commercial manufacture of Sandoz's Product within the United States, or importation of Sandoz's Product into the United States, during the term of the '994 patent would infringe claims 1-8 of the '994 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

31. Novo Nordisk will be harmed substantially and irreparably if Sandoz is not enjoined from infringing the '994 patent.

32. Novo Nordisk has no adequate remedy at law.

33. Novo Nordisk is entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 8,114,833

34. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-33 of this Complaint.

35. Sandoz has infringed the '833 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Sandoz's ANDA, by which Sandoz seeks approval from the FDA to sell, offer to sell, use, and/or engage in the commercial manufacture of Sandoz's Product prior to the expiration of the '833 patent.

36. Claims 1-15 of the '833 patent are directed to GLP-1 formulations. Claims 16-31 are directed to methods for preparing such formulations or methods of reducing deposits or reducing clogging by replacing the isotonicity agent in a formulation with propylene glycol. Sandoz's sale, offer for sale, use, or commercial manufacture of Sandoz's Product within the United States, or importation of Sandoz's Product into the United States, during the term of the '833 patent would infringe claims 1-31 of the '833 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

37. Novo Nordisk will be harmed substantially and irreparably if Sandoz is not enjoined from infringing the '833 patent.

38. Novo Nordisk has no adequate remedy at law.

39. Novo Nordisk is entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 8,579,869

40. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-39 of this Complaint.

41. Sandoz has infringed the '869 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Sandoz's ANDA, by which Sandoz seeks approval from the FDA to sell, offer to sell,

use, and/or engage in the commercial manufacture of Sandoz's Product prior to the expiration of the '869 patent.

42. Claims 1-6 of the '869 patent are directed to a needle mount. Sandoz's sale, offer for sale, use, or commercial manufacture of Sandoz's Product within the United States, or importation of Sandoz's Product into the United States, during the term of the '869 patent would infringe claims 1-6 of the '869 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

43. Novo Nordisk will be harmed substantially and irreparably if Sandoz is not enjoined from infringing the '869 patent.

44. Novo Nordisk has no adequate remedy at law.

45. Novo Nordisk is entitled to a finding that this case is exceptional and to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 8,846,618

46. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-45 of this Complaint.

47. Sandoz has infringed the '618 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Sandoz's ANDA, by which Sandoz seeks approval from the FDA to sell, offer to sell, use, and/or engage in the commercial manufacture of Sandoz's Product prior to the expiration of the '618 patent.

48. Claims 1-3 and 5-14 of the '618 patent are directed to pharmaceutical formulations comprising liraglutide wherein the pharmaceutical formulation has a pH from 7.5 to 9.4. Sandoz's sale, offer for sale, use, or commercial manufacture of Sandoz's Product within the United States, or importation of Sandoz's Product into the United States, during the term of the '618 patent would infringe claims 1-3 and 5-14 of the '618 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

49. Novo Nordisk will be harmed substantially and irreparably if Sandoz is not enjoined from infringing the ’618 patent.

50. Novo Nordisk has no adequate remedy at law.

51. Novo Nordisk is entitled to a finding that this case is exceptional and to an award of attorneys’ fees under 35 U.S.C. § 285.

COUNT FOR INFRINGEMENT OF U.S. PATENT NO. 9,265,893

52. Novo Nordisk re-alleges and incorporates by reference the allegations of Paragraphs 1-51 of this Complaint.

53. Sandoz has infringed the ’893 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting Sandoz’s ANDA, by which Sandoz seeks approval from the FDA to sell, offer to sell, use, and/or engage in the commercial manufacture of Sandoz’s Product prior to the expiration of the ’893 patent.

54. Claims 1-6 of the ’893 patent are directed to a push button connection for an injection device. Sandoz’s sale, offer for sale, use, or commercial manufacture of Sandoz’s Product within the United States, or importation of Sandoz’s Product into the United States, during the term of the ’893 patent would infringe claims 1-6 of the ’893 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

55. Novo Nordisk will be harmed substantially and irreparably if Sandoz is not enjoined from infringing the ’893 patent.

56. Novo Nordisk has no adequate remedy at law.

57. Novo Nordisk is entitled to a finding that this case is exceptional and to an award of attorneys’ fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Novo Nordisk prays for a judgment in its favor and against Sandoz and respectfully requests the following relief:

A. A judgment that Sandoz has infringed the '343 patent;

B. A judgment that Sandoz has infringed the '994 patent;

C. A judgment that Sandoz has infringed the '833 patent;

D. A judgment that Sandoz has infringed the '869 patent;

E. A judgment that Sandoz has infringed the '618 patent;

F. A judgment that Sandoz has infringed the '893 patent;

G. A judgment, pursuant to 35 U.S.C. § 271(e)(4)(B), preliminarily and permanently enjoining Sandoz, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, from manufacturing, using, offering to sell, or selling Sandoz's Product within the United States, or importing Sandoz's Product into the United States, prior to the expiration of the '343, '994, '833, '869, '618, and '893 patents, including any extensions, adjustments, and exclusivities;

H. A judgment ordering that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Sandoz's ANDA, under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)), shall not be earlier than the expiration of the '343, '994, '833, '869, '618, and '893 patents, including any extensions, adjustments, and exclusivities;

I. If Sandoz commercially manufactures, uses, offers to sell, or sells Sandoz's Product within the United States, or imports Sandoz's Product into the United States, prior to the expiration of the '343, '994, '833, '869, '618, and '893 patents, including any extensions,

adjustments, and exclusivities, a judgment awarding Novo Nordisk monetary relief, together with interest;

J. Attorneys' fees in this action as an exceptional case pursuant to 35 U.S.C. § 285;

K. Costs and expenses in this action; and

L. Such other relief as the Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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June 3, 2020